AD_____

MIPR NO: 94MM4581
93MM3555
92MM2560

TITLE: SUPPORT OF THE CENTER FOR PROSTATE DISEASE RESEARCH AT WALTER REED ARMY INSTITUTE OF RESEARCH

PRINCIPAL INVESTIGATOR: Judd W. Moul, LTC, MC

CONTRACTING ORGANIZATION: Uniformed Services University
of Health Sciences
F. Edward Herbert School of Medicine
4301 Jones Bridge Road
Bethesda, Maryland 20814-4799

REPORT DATE: October 25, 1994

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick
Frederick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
distribution unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	October 25, 1994	Annual Report (8 Feb 93-30 Sep 93)

4. TITLE AND SUBTITLE
Support of the Center for Prostate Disease Research at the Walter Reed Army Institute of Research

5. FUNDING NUMBERS
MIPR Nos.
94MM4581
93MM3555
92MM2560

6. AUTHOR(S)
Judd W. Moul, LTC, MC
David G. McLeod, COL

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Uniformed Services University of Health Sciences
F. Edward Herbert School of Medicine
4301 Jones Bridge Road
Bethesda, Maryland 20814-4799

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick
Frederick, Maryland 21702-5012

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

The Center For Prostate Disease Research (CPDR), a cooperative clinical and basic science research initiative focusing on prostate cancer and disease, began operations 14 September 1992 and this report summarizes the second year of operation. The CPDR is a research collaboration between the Uniformed Services University of the Health Sciences (USUHS), Walter Reed Army Medical Center (WRAMC) Urology Program, and the Armed Forces Institute of Pathology (AFIP) Genito-urinary Pathology Department. Regarding clinical research, a comprehensive prostate cancer patient database has been established with prospective data gathering on all patients from WRAMC. A retrospective database of all patients treated at WRAMC since 1980 is also underway. A serum and tissue bank for all prostate cancer patients at WRAMC has also been established. Regarding basic research, a fully equipped molecular biology laboratory has been established at USUHS for the exclusive study of the molecular genetics and cellular markers in prostate cancer and disease. The full collaborative cooperation between clinicians, clinical researchers, and basic scientists within CPDR has already been productive. The group has reported a commonly mutated region in the Androgen Receptor (AR) gene in advanced prostate cancer. Work is ongoing to determine the clinical significance of this genetic alteration. The CPDR group is excited and enthusiastic to continue with the clinical and basic research study of prostate cancer and disease within the DoD health care system and university.

14. SUBJECT TERMS
Prostate, Cancer, Database, Molecular Biology

15. NUMBER OF PAGES

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the US Army.

____ Where copyrighted material is quoted, permission has been obtained to use such material.

____ Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

____ Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

____ In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

JWM For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

JWM In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

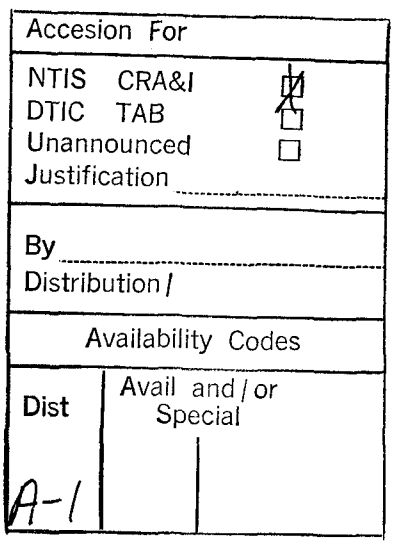
JWM In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

____ In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

25 OCT 94

PI - Signature Date

TABLE OF CONTENTS



PROGRESS REPORT

PRINCIPAL INVESTIGATOR: JUDD W. MOUL, MD, LTC, MC, USA

DEPARTMENT OF: SURGERY, UROLOGY

94MM4581, 93MM3555, 92MM2560
MDA - 905-92-C-0009

INTRODUCTION/SUMMARY STATEMENT

This progress report covers the second year of existence of the Center for Prostate Disease Research (CPDR), a collaborative research program of the Uniformed Services University of the Health Sciences (USUHS), the Walter Reed Army Medical Center (WRAMC) the and Institute of Research (WRAIR), and the Armed Forces Institute of Pathology (AFIP). The Center is involved in the study of the molecular biology of prostate disease through laboratory activities at USUHS and the clinical study of prostate patients and pathology of the prostate at WRAMC and AFIP. The main goal of CPDR is to integrate both basic and clinical study of prostate cancer to bring basic science advances to the clinical benefit of prostate cancer patients.

The CPDR laboratory is housed in rooms A-3009 & A-3018 and contains approximately 1,500 sq. ft. of space within the Department of Surgery at USUHS and is a fully-equipped molecular biology laboratory. Five full-time researchers and several part-time research students are utilizing this facility. The CPDR laboratory is also being utilized for training of Urology residents from Walter Reed in the field of molecular biology of prostate cancer. There is formal

invitation for the National Naval Medical Center, Bethesda, MD, to participate in these efforts. CPDR clinical activities are based at the Urology Service, Department of Surgery at WRAMC. A 150 sq. ft. office houses two full-time employees and a number of part-time researchers. A clinical database of all prostate cancer patients treated at WRAMC is underway which is integrated with pathologic and molecular studies.

BODY

a) Personnel

NAME	FUNDING SOURCE	START DATE	STOP DATE	FT/PT	JOB DESCRIPTION
Judd W. Moul, LTC, MC	Military	09/14/92	NA	FT	Director, CPDR
David G. McLeod, COL, MC	Military	09/14/92	NA	FT	Chief of Urology, WRAMC
F.K. Mostofi, MD	AFIP	09/14/92	NA	PT	Pathologist
Isabell A. Sesterhenn, MD	AFIP	09/14/92	NA	PT	Pathologist
Stephen A. Sihelnik, LTC, MC	Military	09/14/92	NA	PT	Clinical Researcher
Shiv K. Srivastava, PhD	HJF	05/01/93	NA	FT	Director, CPDR Laboratory
Jaya Gaddipatti, PhD	HJF	10/01/93	NA	FT	Molecular Biologist
Dorothy Tong	HJF	05/01/94	NA	FT	Molecular Biologist
Juli Harris, BA	HJF	10/01/93	NA	FT	Clinical DBase Coordinator
Rene Mooneyhan, BA	HJF	06/20/94	NA	FT	Clinical DBase Researcher
Shirley L. Craig	HJF	05/09/94	NA	FT	Administrative Assistant
Denise Young	HJF	01/15/94	NA	PT	Pathology Technician
Roger Connelly, MS	HJF	09/19/94	NA	PT	Biostatistician
Paul H. Maher, BS	HJF	11/16/92	05/01/94	FT	Database Researcher
Michelle L. Dixon	HJF	05/10/93	03/24/94	FT	Secretary
Magda Szuszkiewicz	HJF	92-94 summers		PT	Research Assistant (Student)
Sravant Lavu	HJF	01/01/93	NA	PT	Research Assistant (Student)
Howard Heidenberg, MAJ, MC	Military	07/01/93	NA	FT	Urology Research Resident
Michael Finger, MAJ, MC	Military	07/01/93	NA	FT	Urology Research Resident
Thomas Douglas, CPT, MC	Military	07/01/94	NA	FT	Urology Research Resident
John Bauer, MAJ, MC	Military	07/01/94	NA	FT	Urology Research Resident
Lucille Washington, BS	USUHS	11/13/89	06/01/94	FT	Research Biologist

b) Programs/Projects

1. Prostate Cancer Clinical Database

A major CPDR initiative is to collet demographic, medical, pathologic, and outcomes data on all prostate cancer patients treated at WRAMC and to expand this collection to other DoD health care facilities. The project has a retrospective component (collecting data on all patients treated at WRAMC

since 1980), and a prospective component focusing on complete data collection of all patients seen since 1 January 1994. This project has been approved by the Department of Clinical Investigation (DCI) at WRAMC and copies of data collection forms are attached as Addendum 1. The forms have been used both for patient care progress notes and for CPDR data collection. Hard copy research files have been established for over 2000 patients and are housed in the CPDR office at WRAMC. Double data entry with quality assurance and security precautions are utilized to enter data into a relational database with database support assistance from DCI at WRAMC. WRAMC is the alpha-site for this clinical data collection and the system will be exported to other DoD facilities for similar data collection.

2. Prospective Prostate Cancer Tissue Collection Project

In collaboration with the AFIP, all radical prostatectomies performed for prostate cancer at WRAMC are processed for CPDR research per a WRAMC DCI-approved protocol. AFIP pathology personnel come into the operating room and immediately collect fresh prostate cancer tissue and snap-freeze it for future molecular study. A strict protocol is followed for whole-mounting of the specimens for pathologic research studies. Multicentricity and volume of the tumor are determined, and tissue sections are processed for various immunohistochemical studies. As of the end of this report period, over 100 prospective specimens have been collected and cataloged. These tissues serve as the basis for CPDR laboratory studies at USUHS. Recently CPDR began collecting a portion of prostate tumor from each case for short-term cell culture and gene-therapy studies.

3. CPDR Molecular Biology Laboratory

The ongoing initiative at USUHS is involved in the study of oncogenes, tumor suppressor genes, and other molecular markers and factors in prostate cancer and benign prostate diseases. The following is a listing of ongoing projects:

a. P53 tumor suppressor gene - a survey of tumor suppressor gene p53 mutations in various stages of prostate cancer utilizing immunohistochemistry and gene sequencing has been completed and has been submitted for publication (Heidenberg, et al. - see below) Our studies have shown the involvement of p53 gene alterations in a high fraction of hormone refractory prostate cancer.

b. Androgen Receptor (AR) mutations in prostate cancer - this project has been the main laboratory focus over this reporting period, and the group has examined in excess of 100 prostate cancer specimen for mutations in the AR gene. A major finding has been frequent detection of a specific AR mutation in a significant percentage of advanced prostate cancer cases (Gaddipatti, et al., - see below). Work is ongoing to determine the frequency and significance of these mutations in early, as well as metastatic prostate cancer.

c. Gene therapy of Prostate Cancer: <u>In vito</u> experiments with p53 adenovirus transfection. In collaboration with Dr. Prem Seth (Medicine Branch NIH), we have developed adenovirus vectors containing the tumor suppressor gene p53. We have obtained very exciting results in demonstrating that adenovirus p53 vectors have dramatic inhibitory effects on the growth of metastatic prostate cancer cell lines. Further studies are in progress to follow up these observations in animal models and to design strategies for clinical trials. For this research, the CPDR has received a Research Award form the Association for the Cure of Cancer of the Prostate (CaP Cure). We have also initiated projects to develop the adenovirus vector containing normal AR gene to see if we can correct defects of mutated AR using this approach.

d. Development of primary cell culture from prostate tumor specimens: We have established protocols for growing normal and prostate tumor derived cultures of epithelial cells. This work is extremely important for studies which require a pure population of tumor cells. This study also has utility for future testing of antitumor agents as there are very few prostate cancer cell lines available.

4. Translational and clinical prostate cancer projects - there are a number of other research projects involving collaborations with outside researchers/institutions or research involving the CPDR database and laboratory personnel:

a. RT-PCR of PSA gene to assess occult micrometastasis in prostate cancer. A VA research grant was written with the University of Washington, Seattle, and the Seattle VA Hospital to fund this project. The grant was approved for $65,000 for two years during this reporting period and work will commence during FY 1995.

b. Neural Network artificial intelligence computer programs to assess prostate cancer using clinical variables from the CPDR database. Collaboration with Kaman Sciences Corporation is ongoing to predict outcomes of CaP patients based on pre-treatment clinical and pathologic variables.

c. Cathepsin-D and EGFR expression in prostate cancer as prognostic markers. Collaboration with Medical College of Virginia and University of North Carolina. (One publication in press, [see Maygarden, et al.], and a final report-second publication in progress)

d. Racial variation in diagnostic, treatment, and outcome variables in patients with prostate

cancer: Comparison of radical prostatectomy between black and white patients, PSA variation between black and white prostate cancer patients.

e. Clinical review of PSA-detected prostate cancers (stage T1C) in patients undergoing radical prostatectomy.

f. Clinical trials with Eastern Cooperative Oncology Group (ECOG) at WRAMC.

CONCLUSIONS

The Center for Prostate Disease Research (CPDR) program project has made significant progress in the second year of operations. Our mission to advance knowledge of prostate cancer and disease and to integrate clinical and basic scientists and projects is continuing and expanding. The main advances during this reporting period have been the growth of the CPDR clinical database, the studies of p53 gene and androgen receptor gene alterations in prostate cancer, development of gene therapy experiments, and the general growth and solidification of our program as a national resource for the study for prostate disease.

A. REFERENCES CPDR publications during reporting period :

Moul JW, Lewis DJ, Ross AA, Kahn DG, Ho CK, and McLeod DG: Immunocytological detection of prostate cancer pelvic lymph node micro metastasis: correction to preoperative serum prostate specific antigen. Urology 43:68-73, 1994.

Moul JW: An important goal of prostatectomy: Minimizing incontinence. Contemp Urol, 6(3):15-28, 1994.

Moul JW: For incontinence after prostatectomy, tap a diversity of treatments. Contemp Urol, 6(4):78-88, 1994.

Gaddipati JP, McLeod DG, Heidenberg HB, Sesterhenn IA, Finger MJ, Moul JW, and Srivastava S: Frequent detection of codon 877 mutation in the androgen receptor gene in advanced prostate cancers. Cancer Research, 54:2861-2864, 1994.

Moul JW: Prostatic cancer and BPH, Postgrad Med 96(1):24-25, 1994. (letter)

REFERENCES (Cont.)

Moul JW: Treatment-Post-prostatectomy incontinence. In: Clinicians Desk Reference:Assessment, Treatment, and Management of Incontinence. Spartanburg, SC:HIP, Inc., 1994.

Multidisciplinary Incontinence Clinic Task Force (including Moul, JW):The Pelvic Health Center:People gaining bowel and bladder control. In: Guidelines and Recommendations for Two Models of Continence Care. Spartanburg, SC: HIP, Inc, 1994.

Trotter J, Greenstein F, Hom R, McLeod DG, Moul JW, Reich P, and Smith B:GNRH agonists for the treatment of advanced prostate cancer:managed care implications. Med Interface 7(7)Supplement; 14-32, 1994.

Heidenberg HB, Moul JW, Mostofi FK, and McLeod DG: Clinically detected carcinoma of the prostate treated by radical prostatectomy in a 29 year old man. J Urol 152:966-967, 1994.

Maygarden SJ, Novotny DB, Moul JW, Bae VL, and Ware JL:Evaluation of cathepsin D and epidermal growth factor receptor in prostate carcinoma. Mod Path (In Press)

Heidenberg HB, Sesterhenn IA, Gaddipati P, Weghorst CM, Buzard GS, Moul JW, and Srivastava S:Alterations of the tumor suppressor gene p53 in a high fraction of treatment resistant prostate cancer. J Urol (submitted)

Schenkman NS, Giangeruso E, and Moul JW:Autologous blood transfusion for radical prostatectomy:the use of whole blood vs. packed cells. Urol (submitted)

Zhao L, Chung LWK, Symmans WF, Moul JW, Hall MC, Ye M, Zhau HE:Comparison of the histopathologic grades of prostate cancers in American, Chinese, and Japanese patients. Int J Cancer (submitted)

McLeod DG:Prostate Cancer: Past, Present and Future. In Dawson and Vogelzang, Wiley-Liss, NY. Prostate Cancer, 1-18, 1994

Moul JW, Gaddipati J, Srivastava SK:Molecular biology of prostate cancer:Oncogenes and tumor suppressor genes. In:NA Dawson and Vogelzang, JN (Eds.) Current Clinical Oncology:Prostate Cancer, Wiley-Liss, New York, 1994.

McLeod DG, Moul JW:Controversies in the treatment of prostate cancer with maximal androgen deprivation. In: PJ Walther (Ed.), Controversies and Advances in Urologic Oncology, Surgical Oncology Clinics of North America, WB Saunders, Philadelphia, 1995 (in press)

Moul JW:Oncogenes and tumor suppressor genes in prostate cancer. In:TA Stamey (Ed), 1995 Monographs in Urology, Medical Directions Pub Co, Montverde, FL, 1995 (in press)

REFERENCES (Cont.)

Moul JW:Neoadjuvant hormonal therapy in clinically localized prostate cancer. In" SN Rous (Ed), 1996 Urology Annual, Norton, New York, 1996 (in press)

McLeod DG, O'Brien ME:Hormonal management of metastatic prostate cancer and quality of life issues. In: NI Vogelzang, PT Scardino, WU Shipley, DS Coffey (Eds)Comprehensive Textbook of Genitourinary Oncology, Williams and Wilkins, Baltimore, MD, 1995 (in press)

B. PUBLISHED ABSTRACTS CPDR during reporting period:

Moul JW, Maher PD, Schenkman NS, Ware JL, and Maygarden SL:Cathepsin-D and epidermal growth factor receptor protein expression as clinically useful markers in clinically localized adenocarcinoma of the prostate. J Urol, 151:235A (#235), 1994.

McLeod DG, Maher PD, Schenkman NS, and Moul JW:Comparison of radical prostatectomy in white and black patients in an equal-access health care system. J Urol, 151:304!(#305), 1994.

Heidenberg H, Sesterhenn I, Gaddipati J, Weghorst C, Buzard G, Moul J, Srivastava S:Alteration of the tumor suppressor gene p53 in a high fraction of treatment resistant prostate cancer. Society for Basic Urologic Research, May 13-14, 1994.San Francisco Abs # ONC 61.

Gaddipati J, McLeod D, Heidenberg H, Sesterhenn I, Finger M, Moul J, Srivastava S:Frequent detection of codon 877 mutation in the androgen receptor gene in advanced prostate cancers. The Molecular Basis of Cancer Meeting, June 16-18, 1994, Frederick, MD. Abst #65.

Heidenberg H, Sesterhenn I, Gaddipati J, Weghorst C, Buzard G, Moul J, Srivastava S:Alteration of the tumor suppressor gene p53 in a high fraction of treatment resistant prostate cancer. The Molecular Basis of Cancer Meeting. June 16-June 18, 1994. Frederick, MD. Abst #86

WALTER REED ARMY MEDICAL CENTER
Personal Data - Privacy Act of 1974 (PL 93-579)
Urology Clinic-WRAMC

DIVISION: WALTER REED AMC
Automated Version of SF 600
BBIA

REGISTRATION

Patient Rank: 1 Officer 2 Enlisted **Marital Status**: 1 Single 2 Married 3 Divorced 4 Widowed 5 Unk

Ethnic Origin: 1 African-American 2 Caucasian 3 Asian 4 Hispanic 5 Other:_____.

Height:_____ft._____in.

Weight:_____lbs.

PATIENT MEDICAL HISTORY:

Family History of CAP? 0 No 1 Yes 2 Unk

# of 1st degree affected:_____ (Father, Brother, Son)

# of 2nd degree affected:_____ (Grandfather, Uncle, Cousin)

Alcohol Use: 1 ☐ 0-1 drinks per day
2 ☐ more than 1 drink per day

Tobacco Use: 0 ☐ No 1 ☐ Yes

Cigs: 0 Current 1 Past 2 Never 3 Unk

Pipe: 0 Current 1 Past 2 Never 3 Unk

Cigars: 0 Current 1 Past 2 Never 3 Unk

Pre-tx Potency: 0 No 1 Yes 2 Unk

Treated BPH: 0 No 1 Yes 2 Unk

Treatment of BPH (Check all that apply):

1 ☐ Alpha Block
2 ☐ 5 Alpha Reductase
3 ☐ Surgery
4 ☐ Other:_____.

Vasectomy: 0 ☐ No 1 ☐ Yes 2 ☐ Unk

Age: ☐ < 30 (1) ☐ 30-34 (2) ☐ 35-39 (3) ☐ > 40 (4)

COPD: 0 No 1 Yes 2 Unk

CAD: 0 No 1 Yes 2 Unk

HTN: 0 No 1 Yes 2 Unk

CVA: 0 No 1 Yes 2 Unk

Renal Insuf.: 0 No 1 Yes 2 Unk

Diabetes: 0 No 1 Yes 2 Unk

Other Cancer: 0 No 1 Yes 2 Unk

Specify:_____.

SYMPTOMS:

None:	0 No	1 Yes	2 Unk
Prostatism:	0 No	1 Yes	2 Unk
Perineal Pain:	0 No	1 Yes	2 Unk
SX of Metastasis:	0 No	1 Yes	2 Unk
Hematospermia:	0 No	1 Yes	2 Unk
Gross Hematuria:	0 No	1 Yes	2 Unk

REASON FOR BIOPSY:

ABNDRE:	0 No	1 Yes	2 Unk
Elev. PSA:	0 No	1 Yes	2 Unk
PSA Velocity:	0 No	1 Yes	2 Unk
Other:	0 No	1 Yes	2 Unk

Specify:_____.

BIOPSY RESULTS:

Diagnosis Date: D_____M_____Y_____.

Number of Biopsies:_____. Number of Pos Biopsies:_____.

Location of Pos Biopsy (**Worst grade, worst gleason sum**): Specific Location (if known):

LEFT SIDE: 0 Neg 1 Pos 2 Not Done — L. Apex L. Mid L. Base L. SV

Grade: W M P Gleason Sum:_____ — R. Apex R. Mid R. Base R. SV

RIGHT SIDE: 0 Neg 1 Pos 2 Not Done

Grade: W M P Gleason Sum:_____

UNKNOWN SIDE: 0 Neg 1 Pos 2 Not Appl.

Grade: W M P Gleason Sum:_____

BIOPSY TYPE (Circle)

1 TRUS-Findings: 0 Neg 1 Pos 2 Unk
Vol:_____ cc's

2 Digitally-Directed Transrectal

3 TURP

4 Other/Specify:_____.

PRE-BIOPSY PSA:_____D_____M_____Y_____.

SOAP NOTE:

PX Name:_____ Prefix/SSN: _____ Physician's Signature:_____

WALTER REED ARMY MEDICAL CENTER
Personal Data - Privacy Act of 1974 (PL 93-579)
Urology Clinic-WRAMC

DIVISION: WALTER REED AMC
Automated Version of SF 600
BBIA

STAGING

PRETREATMENT LAB VALUES (Check all that apply or enter value if known)

Creatinine:_____ D_____M_____Y_____. Alk Phosphatase:_____ D_____M_____Y_____.

Testosterone:_____ D_____M_____Y_____. Pre-Tx PSA:_____ D_____M_____Y_____.

Pre-Tx PAP:_____D_____M_____Y_____.

RADIOLOGY (Circle):

Bone Scan:	0 Neg	1 Pos	2 ND	3 Pending
MRI-Pelvis:	0 Neg	1 Pos	2 ND	3 Pending
MRI-Transrectal:	0 Neg	1 Pos	2 ND	3 Pending
CT Scan ABD:	0 Neg	1 Pos	2 ND	3 Pending
CT Scan Pelvis:	0 Neg	1 Pos	2 ND	3 Pending
CXR:	0 Neg	1 Pos	2 ND	3 Pending
IVP:	0 Neg	1 Pos	2 ND	3 Pending
CYSTO:	0 Neg	1 Pos	2 ND	3 Pending

FINAL CLINICAL STAGE (PRE-TREATMENT)

1 A1	6 C1
2 A2	7 C2
3 B0	8 C3
4 B1	9 D0
5 B2	10 D1
	11 D2

FINAL TNM STAGE (PRE-TREATMENT)

1 T1a	7 T3a	1 NX	1 MX
2 T1b	8 T3b	2 N0	2 M0
3 T1c	9 T3c	3 N1	3 M1
4 T2a	10 T4a	4 N2	
5 T2b	11 T4b	5 N3	
6 T2c			

PRIMARY TREATMENT:

1 Prostatectomy 2 Hormonal 3 Radiation 4 Watch Wait 5 Decision Pending

SOAP NOTE:

Patient's Name:_____ Last Four:_____ Physician's Signature:_____

Patient's Name:_____ Last Four:_____ Physician:_____.

RADICAL PROSTATECTOMY

Date of Prostatectomy: Day _____Month_____Year_____.

Operation Time: Hours_____Minutes_____.

Lymphadenectomy: 1 Open 2 Laparoscopic

Type: 1 Retropubic 2 Perineal

Nerve Sparing: 1 Unilateral 2 Bilateral 3 Not Done

HCT: Pre-Op_____Day_____Month_____Year_____.

Post-Op (first value on post op day 1)_____.

Autologous Blood Collected: 0 No 1 Yes 2 Unk

# of Units_____.

Estimated Blood Loss (during surgery):_____cc's

Transfusion Units (intraoperative): ATOL_____ Non ATOL_____.

Was Preoperative Hormone Manipulation Used? 0 No 1 Yes 2 Unk

Type (Circle): Flutamide Proscar

Lupron Zoladex

Other:_____.

Duration (weeks):_____.

RADIATION TREATMENT SUMMARY
WALTER REED ARMY MEDICAL CENTER

Date:_____.

Last Name:_____First Name:_____MI:_____SSN:_____.

Date of Birth: D_____M_____Y_____ Diagnosis:_____Histology:_____.

Gleason Sum:_____. Stage: T_____N_____M_____.

1 ☐ From Biopsy

2 ☐ From Surgery

Pre-treatment Lab Values: PSA_____PAP_____.

TREATMENT

Start Date: D_____M_____Y_____. Elapsed Days_____. (include start and stop date)

Completion Date: D_____M_____Y_____.

# of Fractions:_____.

Fraction Size:_____cGy

Field Arrangement:	Energy:	Dose:	Field Size:
1 ☐ 4 Field	1 ☐ 6 MV	Pelvis:_____cGy	AP-PA:____ ____.____X____ ____.____.
2 ☐ Arc	2 ☐ 15 MV	Prostate + SV:_____cGy	R/L Lat:____ ____.____X____ ____.____.
3 ☐ Other	3 ☐ Mixed	Prostate:_____cGy	

TREATMENT RESPONSE

Rectal SX: 1 ☐ Diarhhea 3 ☐ Other 2 ☐ Proctitis	Management:
G-U SX: 1 ☐ Frequency 3 ☐ Dysuria 2 ☐ Hematuria 4 ☐ Other	Management:
Skin SX: 0 ☐ No 1 ☐ Yes	Management:
Breaks in Treatment: 0 ☐ No 1 ☐ Yes	Describe:

FOLLOW UP

PSA at Completion of RT:_____ Date: D_____M_____Y_____ F/U Clinic 4 Weeks:_____.

Physician Signature:_____.

RADIATION THERAPY FOLLOW-UP
WALTER REED ARMY MEDICAL CENTER

Date:_____.

Name:_____ SSN:_____

Surgery: 0☐ No 1☐ Yes Date: D_____ M_____Y_____

Radiation Dose:_____ Completion Date: D_____M_____Y_____

Hormone Therapy: 0☐ No 1☐ Yes Date Therapy Began: D_____M_____Y_____

Orchiectomy: 0☐ No 1☐ Yes Date: D_____M_____Y_____

Original Stage: T_____N_____M_____.

PSA: Pre-treatment:_____.

Immediate Post Treatment:_____.

Current:_____.

Hormone Failure: 0☐ No 1☐ Yes

CANCER SYMPTOMS/COMPLICATIONS

Weight Loss: 0☐ No 1☐ Yes	Fatigue: 0☐ No 1☐ Yes	Night Sweats: 0☐ No 1☐ Yes	Febrile Episodes: 0☐ No 1☐ Yes
Bone Pain: 0☐ No 1☐ Yes Site:			

GASTROINTESTINAL SYMPTOMS

Diarrhea: 0☐ No 1☐ Yes Frequency: 1☐ Daily 3☐ Monthly 2☐ Weekly 4☐ Less	Constipation: 0☐ No 1☐ Yes Frequency: 1☐ Daily 3☐ Monthly 2☐ Weekly 4☐ Less
BRBPR: 0☐ No 1☐ Yes Frequency: 1☐ Daily 3☐ Monthly 2☐ Weekly 4☐ Less	Melena: 0☐ No 1☐ Yes Frequency: 1☐ Daily 3☐ Monthly 2☐ Weekly 4☐ Less
Incontinence: 0☐ No 1☐ Yes Frequency: 1☐ Daily 3☐ Monthly 2☐ Weekly 4☐ Less	Pain: 0☐ No 1☐ Yes Frequency: 1☐ Daily 3☐ Monthly 2☐ Weekly 4☐ Less

GENITOURINARY SYMPTOMS

Hematuria: 0☐ No 1☐ Yes Frequency: 1☐ Daily 3☐ Monthly 2☐ Weekly 4☐ Less	Urinary Frequency: 0☐ No 1☐ Yes Frequency: 1☐ Daily 3☐ Monthly 2☐ Weekly 4☐ Less
Dysuria: 0☐ No 1☐ Yes Frequency: 1☐ Daily 3☐ Monthly 2☐ Weekly 4☐ Less	Decreased Erectile Function: 0☐ No 1☐ Yes Frequency: 1☐ Daily 3☐ Monthly 2☐ Weekly 4☐ Less
Nocturia: 0☐ No 1☐ Yes Frequency (Episodes Per Night): _____	Incontinence: 0☐ No 1☐ Yes Pads/Day: 1☐ < One 2☐ One 3☐ > One

PHYSICAL EXAM

Vital Signs: Temp:_____ Pulse:_____ Respirations:_____ Blood Pressure:_____	Rectal: Tone:_____ Fissure:_____ Hemorrhoids:_____ Prostate:_____	G-U: Phallus:_____. Scrotum:_____.

HEENT:_____ Lymphadenopathy:_____ Abdomen:_____.

FOLLOW-UP & DISPOSITION

1. Disease Status: 1☐ NED 2☐ PSA Failure 3☐ Clinical Failure Specify:_____.
2. Studies Ordered:_____.
3. Other Orders:_____.
4. Return Appt.: ☐ No ☐ Yes D_____M_____Y_____.

Physician's Signature:_____.

HORMONAL THERAPY

ORCHIECTOMY: 0 No 1 Yes Date: D____ M____ Y____

Total:	0 No	1 Yes	2 Unk	
Subcapsular:	0 No	1 Yes	2 Unk	
Testicular Prostheses:	0 No	1 Yes	2 Unk	

LH-RHa: 0 No 1 Yes Date Started: D____ M____ Y____, Date Terminated: D____ M____ Y____

Type (Circle): Lupron Zoladex Other:_____.

ANTIANDROGEN: 0 No 1 Yes Date Started: D____ M____ Y____

Type (Circle): Flutamide Other:_____.

SOAP NOTE:

Patient's Name:_____ Last Four:_____ Physician's Signature:_____.

WALTER REED ARMY MEDICAL CENTER
Personal Data - Privacy Act of 1974 (PL 93-579)

DIVISION: WALTER REED AMC
Automated Version of SF 600

PROSTATE CANCER FOLLOW-UP

Follow-up Date: D_____M_____Y_____ Protocol: 0 No 1 Yes _____.
New Address : N Y Specify:_____.
New Phone: N Y Specify:_____.

RECURRENCE: 0 ☐ No 1 ☐ Yes Date of Recurrence: D_____M_____Y_____

Type of Recurrence:

Increased PSA: 0 ☐ No 1 ☐ Yes
Pos Bone Scan: 0 ☐ No 1 ☐ Yes
Increased PAP: 0 ☐ No 1 ☐ Yes
Local Recur.: 0 ☐ No 1 ☐ Yes
Visceral Mets: 0 ☐ No 1 ☐ Yes

Diagnosis of Recurrence (NO ENTRY IF NOT DONE):

Bone Scan: 0 ☐ Neg 1 ☐ Pos 2 ☐ Pending
MRI: 0 ☐ Neg 1 ☐ Pos 2 ☐ Pending
CT: 0 ☐ Neg 1 ☐ Pos 2 ☐ Pending
Tissue Bx: 0 ☐ Neg 1 ☐ Pos 2 ☐ Pending
TRUS: 0 ☐ Neg 1 ☐ Pos 2 ☐ Pending

TREATMENT FOR RECURRENCE (Circle all that apply):

Hormonal TURP Radiation Chemo Watchful Wait Other:_____.

CONTINENCE/POTENCY: 0 ☐ New Data 1 ☐ No Change

Continence: 0 ☐ No 1 ☐ Yes
If no, number of pads/day:_____
If yes, month/year continent: M_____Y_____

Potency: 0 ☐ No 1 ☐ Yes
If no, circle Tx: 1 VET 2 ICI 3 Penile Pros 4 Other:_____.
If yes, month/year potent: M_____Y_____.

LABS PENDING (check all that apply or enter value if known):

PSA:_____D____M____Y____PAP:_____D____M____Y____HCT:_____D____M____Y____.
CR:_____D____M____Y____ALK PHOS:_____D____M____Y____TESTOS:_____D____M____Y____.

COMPLICATIONS OF PRIMARY TREATMENT: 0 ☐ No 1 ☐ Yes

If Prostatectomy:

DVT/PE: 0 ☐ No 1 ☐ Yes 2 ☐ Unk
MI/Cardiac: 0 ☐ No 1 ☐ Yes 2 ☐ Unk
Rectal Injury: 0 ☐ No 1 ☐ Yes 2 ☐ Unk
Reoperation: 0 ☐ No 1 ☐ Yes 2 ☐ Unk
Specify:_____.
Other: 0 ☐ No 1 ☐ Yes_____

If Hormonal:

Hot Flashes: 0 ☐ No 1 ☐ Yes 2 ☐ Unk
Diarrhea: 0 ☐ No 1 ☐ Yes 2 ☐ Unk
Surgical: 0 ☐ No 1 ☐ Yes 2 ☐ Unk
Gynecomastia: 0 ☐ No 1 ☐ Yes 2 ☐ Unk
Antiandrogen Stopped: 0 ☐ No 1 ☐ Yes 2 ☐ Unk
Other: 0 ☐ No 1 ☐ Yes_____

SOAP NOTE:

Current Clinical Stage:_____. Disease Status (Circle): 1 NED 2 Alive w/CAP 3 Alive/Unk

Patient's Name:_____ Last Four:_____ Physician's Signature:_____.